Stratton VA Medical Center
IRB Standard Operating Procedure: Protocol Deviations

POLICY

It is Stratton VA Medical Center's policy to comply with all applicable federal, state and local regulations, and ICH guidelines in the conduct of human subject research studies. Written procedures are required for processing reports of deviations.

The IRB's policy requires the Principal Investigator to report to the IRB upon discovery, any "Significant Deviation" to the IRB-approved protocol that may potentially affect the rights, safety, and welfare of the subjects, such as:

a. Administrative or procedural infractions in the implementation of the protocol or informed consent.
b. Significant changes to the IRB-approved protocol that may potentially affect the rights, safety, and welfare of the subjects.

All changes in previously approved protocols must be promptly reported to the IRB. The proposed changes must not be initiated without review and approval except where necessary to eliminate apparent immediate hazards to subjects.

The Principal Investigator(s) may contact the IRB Chair or designee with questions regarding whether or not a potential deviation poses a risk to subjects. The IRB will make the final determination as to the level of risk.

PROCEDURE

Significant Deviations: Any departure from the procedures stated in the approved research protocol or informed consent that increases the risk to subjects. The deviation is required to be reported to the IRB within 5 days of the incident.
Examples include but are not limited to the following:

a. Infractions involving dosing/distribution of study medications causing risk to the subject
b. Infractions in following the guidelines for proper informed consent execution (i.e. using an expired informed consent)
c. Infractions in which the sponsor (if applicable) requests notification to the IRB
d. Infractions in which research procedures performed outside the approved research protocol increased risk to subjects

Principal Investigators must report *Significant Deviations* to the IRB upon discovery, and no later than 5 days, by submitting a letter that will include, but is

not limited to, the following: a description of the deviation, an explanation of why the deviation occurred, a corrective action plan, and an explanation of what is being done to prevent a future occurrence. If the study is a sponsored study, the letter should indicate if the sponsor was notified of the deviation.

Upon receipt of the deviation letter, the IRB staff stamps it with a date of receipt. The information is reviewed for completeness and accuracy by the IRB staff and is entered into the database.

If any items are missing or there are questions about the deviation, the Principal Investigator or the designated contact person may be contacted by the IRB staff and requested to provide additional information or documents.

The IRB Chair or designee, the Research Compliance officer, and the ACOS R&D will review the deviation letter to determine whether any revisions or actions are required and if so, will refer the deviation to the full IRB to review and determine the actions required. The IRB will consider whether the deviation is non-compliance and make a determination whether the non-compliance is serious or continuing. The IRB is notified of all "significant deviations" in the agenda of the next scheduled IRB meeting.

If the IRB Chair or designee or the full IRB request any modification to the consent document or research protocol, or addendum consent, the IRB Chair or designee will send a notification to the Principal Investigator to submit the modifications to the IRB for review.

If the PI does not comply with the IRBs specified request for modifications, the protocol may be suspended or terminated according to, *IRB-SOP: Suspension and Termination of Approved Research*. The PI mat also be prohibited from submitting new research.

If the IRB Chair or designee or the full IRB determines that a significant deviation requires reporting, then:

a. The IRB staff prepares a report of the event and corrective actions to be taken.

b. The IRB staff sends a copy of the report signed by the IRB Chair or designee to the Care Line Leader and the institutional official.

c. A copy of the report is included with the agenda for the next scheduled IRB meeting.

d. The IRB staff forwards a copy of the notification to Office for Human Research Protections (OHRP), Food and Drug Administration (FDA), Office for Research Oversight (ORO), and the sponsor, as applicable, within 10 working days of the IRB's determination.